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Stacey-Ann Miller Date

From Mother to Child: the effect of women's group interventions on infant mortality in developing countries

By

Stacey-Ann Miller

MPH

Hubert Department of Global Health

_____

Amy Webb-Girard, PhD,

Thesis Advisor

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By

Stacey-Ann Miller

BA

Lawrence University

2008

Thesis Advisor: Amy Webb-Girard, PhD

An abstract of
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Abstract

From Mother to Child: the effect of women's group interventions on infant mortality in developing countries

By Stacey-Ann Miller

Although child mortality rates have more than halved since 1960 (from 20 million in 1960 to a little under 10 million children in 2006), there is still work to be done if the global rate of under five mortality will be decreased by two thirds by the year 2015. In the Department of Huehuetenango, the situation is especially dim. Referred to as the "triangle of death", infant mortality and malnutrition rates are the highest in this area of Guatemala, with 68% of children under the age of three being malnourished. As a response to the high rates of child mortality and morbidity, the organizations Curamericas Guatemala and Sistema Integral de Atención de Salud (SIAS) in collaboration with the organization, Global Health Education and Economic Development (Global H.E.E.D) created a women's group intervention.

Women's groups are used widely in developing countries as a mechanism to deliver maternal and child health interventions. However, a paucity of information exists about their effectiveness. This systematic review and meta-analysis will assess the effect of these groups on neonatal mortality, perinatal mortality and stillbirth rates. Additionally, an illustrative case study will be presented on how women's groups are currently being utilized in Calhuitz, Guatemala.

A search of the literature was done to ascertain the effectiveness of women's groups in ensuring better health outcomes for children in developing countries. To carry out this systematic review, the Child Health Epidemiology Reference Group (CHERG) review guidelines were utilized. The search engines used were PubMed, Popline, Embase, Web of Science and the Cochrane Controlled Trials Register in the Cochrane Library. A manual literature search was also done, utilizing the reference sections of abstracted articles. To quantify the effect of women's group interventions on neonatal mortality (NMR), perinatal mortality and stillbirth rates, a meta-analysis was also performed using Review Manager 5.1. The quality of evidence for women's group interventions was also assessed. Information gathered from the meta-analysis and systematic review guided recommendations for the intervention in Guatemala.

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INTRODUCTION

The problem of child mortality in developing countries is a problem that requires continued attention. Although child mortality rates have more than halved since 1960 (from 20 million in 1960 to a little under 10 million children in 2006) (Lawn 2005), there is still work to be done if the global rate of under five mortality will be decreased by two thirds by the year 2015 (Jones, Steketee et al. 2003; UNICEF 2007).

Women's groups are used widely in developing countries as a mechanism to deliver maternal and child health interventions. CARE child survival programs, for example, have used women's groups widely in the promotion of breastfeeding and other behaviours relevant to child health (Charleston 2004; Charleston 2005; Capps 2006; Gopinath 2007; Gopinath 2008). Although the use of mother support groups to facilitate child survival efforts is a mechanism that is well known, there is a paucity of information on the effect that these groups have had on child survival. Furthermore, where interventions have utilized women's groups, the effectiveness of these groups has not been carefully evaluated. The use of mother support groups is not intended to be a "stand alone" intervention but one through which other interventions can be integrated. This systematic review and meta-analysis will review the effect of women's groups on neonatal and perinatal mortality. Using the Child Health Epidemiology Reference Group (CHERG) mechanism of reviewing intervention effects on child survival, the effect of mother support groups on survival of neonates will be deduced. A case study will also be presented of women's groups (self help groups) in Guatemala.

The motivation for this thesis was based on personal experiences with women support groups in the rural, remote village of Calhuitz, Guatemala during the summer of 2010. The child mortality rate for children under the age of five years old in Guatemala as of 2009, was 40 deaths per 1000 live births (Jones 2010). As a response to this alarming rate of child mortality, the organization Curamericas Guatemala and Sistema Integral Atencion de Salud (SIAS) in collaboration with the organization, Global H.E.E.D decided to create an intervention. The intervention was focused on bringing nutritional education to women (of child bearing age) as a means of improving the health of the child. The major component of the intervention was formal monthly group education sessions held by the staff of the Casa Materna. In these group sessions, staff from the Casa materna held workshops with women from each community sector to teach them how to cook healthy foods, to educate them on the nutrients available in those foods and to encourage proper handwashing habits when handling food. In addition, the staff used these workshops to identify mothers and children that may have diseases or illnesses and set up appointments with them to receive services at the clinic.

In addition to reducing child malnutrition, this approach has the ability to reduce infection due to poor hygiene and sanitation practices. From a logical standpoint, helping mothers to improve the health of their children would appear to be a strategy that would lead to a decrease in adverse child outcomes. However, in reality and in different settings this may not be the case. A large amount of stakeholder dollars goes into supporting interventions that can improve health outcomes of children in developing countries. To ensure the scale-up of effective intervention strategies, it is imperative that the impact of different interventions is known. This thesis fills a

gap by addressing the direct impact of women's support groups on facilitating a decrease in infant mortality which leads to increased child survival. The next chapter provides a review of the literature on neonatal mortality, perinatal mortality and women's groups.

BACKGROUND

Approximately nine million children die each year from diseases that are thought to be highly preventable, including but not limited to pneumonia, diarrhea, malaria, malnutrition and neonatal conditions. Of the nine million children dying, 40% of them are under the age of 5 years old and 60% of them are under the age of one year old (UNICEF 2007). Hardest hit by this reality are the countries of Sub-Saharan Africa and South Asia, which together account for approximately 83% of all child deaths in children under the age of five (Rajaratnam, Marcus et al. 2010).

Mortality rates have reduced by 4.5% or more, however, Bangladesh, Bolivia, Nepal, Malawi , Ethiopia, Mozambique and Niger have reduced their absolute mortality rates by more than 100 per 1000 live births since 1990 (Bhutta, Chopra et al. 2010). Major reductions to below 30 per 1000 live births as of 2006 in child mortality have occured in Northern Africa, Eastern Asia, Western Asia, Latin America and the Caribbean and the Commonwealth of Independent States (CIS) (UNICEF 2007).

Although these reductions are promising, the reality remains that more work needs to be done in reducing neonatal mortality rates (NMR). As it now stands, there is slower progress in reducing NMR than mortality rates in children under the age of five. Approximately four million babies die during their first month of life (the neonatal period) and 50% of those babies die during their

first hour of life (Lawn 2005; Black, Cousens et al. 2010). Middle income and low income countries where neonatal deaths are concentrated have overall NMRs of 33 per 1000 livebirths compared to 4 per 1000 livebirths in high income countries. As with under five mortality rates, the majority of newborn deaths occur in South Asia and Sub-Saharan Africa (Lawn 2005), with South Asia accounting for 54% (1.295 million) of neonatal deaths while Sub-Saharan Africa accounts for 29% (1.224 million) of these deaths (Lawn 2005; Black, Cousens et al. 2010).

The situation is not much better in terms of the perinatal period, which encompasses deaths in the first week of life and fetal deaths (stillbirths). Approximately 6.3 million perinatal deaths occur per year, with half of these attributed to stillbirths (WHO, 2006). Geographically, perinatal mortality is most prevalent in South Asia and Sub-Saharan Africa, with these regions accounting for 50 and 62 per 1000 births respectively (Osrin and Prost 2010). The high burden of still births (98%) is also concentrated in these areas (Mullan and Horton 2011).

Leading causes of neonatal and perinatal death

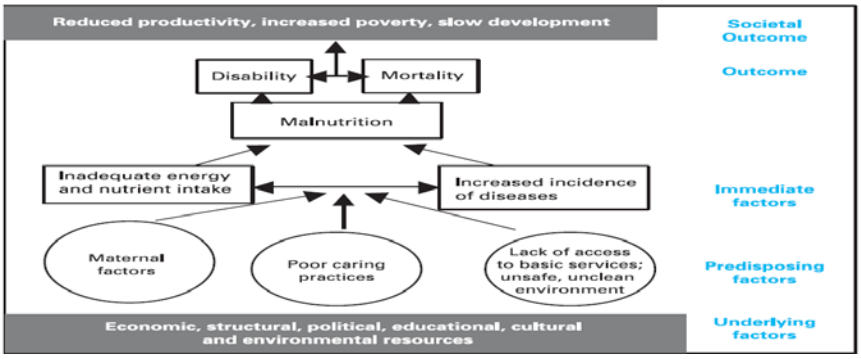
Infections (excluding tetanus), birth asphyxia and complications of preterm birth are the main causes of neonatal and peinatal deaths. Infections account for almost a million of global neonatal deaths while intrapartum events and complications of preterm birth account for a little over a million deaths (Azad, Barnett et al. 2010; Lawn, Kerber et al. 2010). Together infections, birth asphyxia and complications of preterm births account for 80% of neonatal deaths (Lawn, Kerber et al. 2010). Deaths in the perinatal period are largely due to pregnancy complications, lack of proper nutrition to the growing fetus, genetic abnormalities, infections and diseases of the mother (WHO 2006; Yakoob, Menezes et al. 2009).

Underlying causes of neonatal and perinatal mortality

There are a myriad of reasons to explain the high levels of neonatal mortality in developing countries. These reasons can be understood in the context of the basic, underlying and immediate determinants of child survival as outlined in Figure 1. Consequently some of the underlying and structural reasons influencing child mortality include:

- low numbers of health workers
- slow turnover periods for adoption of evidence based policies
- disparities in family planning services within and between countries
- female illiteracy and empowerment issues
- lack of hygiene and access to safe water
- inadequate feeding practices
- poverty, early pregnancy
- lack of political will
- poor quality of care and the failure of interventions to reach the poorest, isolated, vulnerable , uneducated, marginalized communities that need these interventions the most (Lawn 2005; UNICEF 2010).

Figure 1: UNICEF nutrition conceptual framework



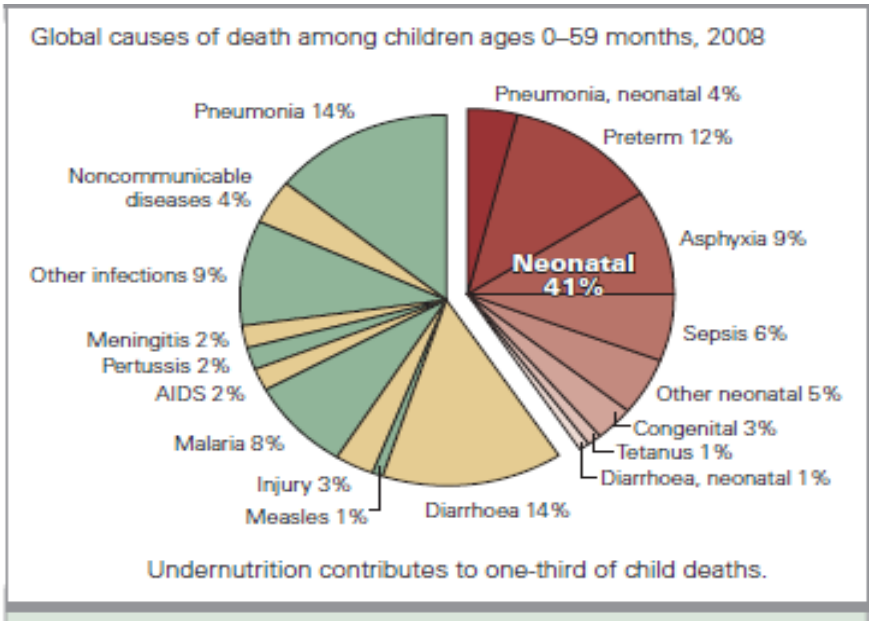
Source: (Atwood 2005)

Interventions to reduce the leading causes of neonatal and perinatal mortality

To reduce neonatal mortality, there are many proven cost effective interventions. These include tetanus toxoid vaccination, exclusive breastfeeding and kangaroo mother care (KMC) for low birth weight babies (Conde-Agudelo, Diaz-Rossello et al. 2003; UNICEF 2007). These interventions address some of the leading causes of death (seen in Figure 2) during the neonatal period. KMC is a technique in which newborns are put close to their parent's chest for 24 hours a day. This helps in transmitting heat from the parent to the newborn, and prevents the newborn from becoming hypothermic. KMC together with exclusive breastfeeding can facilitate reductions in not only hypothermia but also malnutrition (Ruben 2010-2011). A study in 40 South African hospitals found that neonatal mortality was 19% lower in hospitals that utilized KMC than in hospitals that did not utilize KMC (Victora 2010) and a Cochrane review of KMC as a mechanism to reduce mortality and morbidity in low birth weight infants found that there was a significant reduction in severe infection/sepsis (RR 0.57, 95% CI: 0.40-0.80) as a result of

KMC. A study in Rajasthan, India found that tetanus toxoid vaccination led to 88% reduction in neonatal tetanus risk (Gupta 1998).

Figure 2: Leading causes of child mortality



Source: ((UNICEF) 2007)

Community based interventions and Community mobilization

In developing countries, most neonatal and perinatal deaths occur in homes and communities (Bhutta, Darmstadt et al. 2005; Lawn 2005). Interventions to reduce these outcomes are often focused on community mobilization. Community mobilization is "a capacity-building process through which community members, groups or organizations plan, carry out, and evaluate activities on a participatory and sustained basis to improve their health and other conditions,

either on their own initiative or stimulated by others"(Howard-Grabman 2007). It can take many forms; it can take the form of collective action, co-learning, cooperation, consultation, compliance or co-option, with each of these forms varying on the power given to the local people. For example, co-option (at the lowest level) involves very little involvement from local people while collective action involves local people from program inception to the analysis phase of an intervention, without the input of external sources. Participatory approaches at the high end of the spectrum present a departure from conventional methods whereby researchers enter a community and appoint themselves as owners of knowledge while community members are simply beneficiaries of that knowledge (Howard-Grabman 2007).

The idea of allowing people in developing countries the ability to make decisions about their health stemmed from the Alma-Ata declaration of 1978, which stated as one of its tenets that "people have the right and duty to participate individually and collectively in the planning and implementation of their health care" (WHO 1978). Ideally, community mobilization gives people a voice in making decisions about their health. In integrating a community mobilization strategy within a proven intervention, it is ensured that those most affected by the issue are targeted (Howard-Grabman 2007).

One of the ways in which the participatory approach is utilized is through the use of the community action cycle. The participatory approach, through the community action cycle, is one of mutual dialogue between participants in a group and the facilitators, in which the facilitator assists in helping the community members to devising strategies relevant to the issue, is the

source of knowledge about the issue and supports the development of mechanisms for change (Manandhar, Osrin et al. 2004; Tripathy, Nair et al. 2010).

Key steps in this cycle are:

- the identification and prioritization of maternal and neonatal problems in the community (and collection of local information by group members)
- the identification of possible solutions
- the planning, implementation and monitoring of solution strategies
- the discussion of the effects of the strategies

To facilitate these key intervention steps, picture card games, role play, and storytelling is utilized to help community members conceptualize key issues and devise strategies to address these issues (Manandhar, Osrin et al. 2004; Tripathy, Nair et al. 2010)

Targeted Community mobilization: women's groups

In developing countries, almost two thirds of women ages 15 and over are illiterate and less educated than their male counterparts and so less capable of accessing basic health care information (UNICEF 2007). Additionally, in rural, impoverished, paternalistic societies, it is very common that women are discriminated against in terms of health and education. These women, have little or no say in decisions about their health or the health of their children. In fact,

in Mali, Nigeria and Burkina Faso, 75% of women contend that their husbands are the sole decision makers in their household (UNICEF 2007).

Women's support groups have been formed with the aim of encouraging women to engage in decision making about their health and the health of their children. These groups go by several names, mothers' clubs, mothers' organizations, mothers' support groups, mothers' interchange groups, and mother to mother support groups. There is great variation in the literature in the purpose and arrangement of these groups but in general, they consist of a group of women meeting together based on shared issues, views, circumstances and beliefs (Green 1998).

Women's group interventions to address leading causes of neonatal and perinatal mortality

Women's groups have used mechanisms to integrate proven interventions to address the leading causes of neonatal and perinatal deaths. Traditional birth attendants, for example, may be given equipment for neonatal resuscitation (Manandhar, Osrin et al. 2004), health personnel may receive refresher courses on handling newborn complications (Baqui, El-Arifeen et al. 2008) and health workers may be charged with the duty of distributing iron-folate supplements (Baqui, El-Arifeen et al. 2008). A study in Copperbelt province in Zambia found that the training of traditional birth attendants reduced birth asphyxia by 63% (Gill, Phiri-Mazala et al. 2011). Another study in northern India, showed that the training of traditional birth attendants led to a 70% reduction in asphyxia-specific mortality (Kumar 1995). In Gambia, training of TBAs led to a 33% reduction in neonatal mortality related to infections (Bhutta, Darmstadt et al. 2005) while in rural Nepal, there was a lower prevalence of low birth weight when women were

supplemented with iron-folate supplements (Bhutta, Darmstadt et al. 2005). Hence, a focus on neonatal resuscitation, training of health personnel and distribution of supplements help to reduce birth asphyxia, complications due to preterm birth and reductions in neonatal infections.

The indirect impact of women's groups on neonatal and perinatal mortality

Women's groups focus primarily on behaviour change to reduce neonatal and perinatal mortality. The mechanism through which women's groups impact behaviours and ultimately health outcomes is a complex one. According to Kumar et al, there are multiple players along the continuum from behaviour change to a health outcome. These players include the agents of behaviour change, the actors, the behaviours being targeted, direct causes of the outcome and the outcome itself. For women's group interventions, the actors are women of reproductive age or pregnant women. The agents of behaviour change include group meeting facilitators, the women's groups, and health workers. Targeting key behaviours to specific actors, however, doesn't automatically lead to behavioural change. Interventions alone may not effect behavioural changes but coupled with motivation, access to resources and social support may lead to behavioural changes in individuals. Furthermore, for behavioural changes to translate to improvements in health outcomes, the behaviours need to align with the root causes of the prevailing neonatal issues in a particular setting.

Despite this complexity, the literature is inundated with information about the effectiveness of women's groups in improving key behaviours related to infant and child survival. Since breastfeeding is known to help the newborn's immune system fight off infection, CARE child survival projects in Ethiopia (Charleston 2005), Sierra Leone (Capps 2006) and Peru (Charleston

2004) have placed an emphasis on encouraging three practices utilizing women's groups. As a result, they noted improvements in the proportion of women initiating breastfeeding, giving colostrums and exclusively breastfeeding their children (Charleston 2004; Charleston 2005; Capps 2006). For example, in Ethiopia (Charleston 2005), exclusive breastfeeding increased by 22% and the proportion of women giving their child the behaviours increased by 30% from baseline in Ethiopia. In another intervention utilizing support groups, care seeking for pneumonia rose by 57% in Ethiopia (Charleston 2005) and in Sierra Leone (Capps 2006)the percentage of children treated with anti-malarial drugs during a febrile episode increased by almost 21%.

The direct impact of women's groups on neonatal and perinatal mortality

While there is ample research on the indirect impact of women's groups on neonatal and perinatal mortality primarily through encouraging behavioural changes, less is known about the direct effect of these groups on neonatal and perinatal mortality. As neonatal mortality rates continue to increase, it is of paramount importance that interventions having an effect on reducing perinatal and neonatal mortality are identified and utilized, especially in countries where infant mortality continues to be a huge burden.

Few researchers have explored the direct impact of women's groups on neonatal outcomes (Bhutta and Lassi 2010). Furthermore, there are no known reviews that have explored the effect of women's groups on neonatal mortality, perinatal mortality and stillbirths. This systematic

review and meta-analysis serves to fill the gap in knowledge about the effect of women's groups on these outcomes.

METHOD

A search of the literature was done to ascertain the effectiveness of women's groups in reducing neonatal and perinatal mortality in developing countries. To carry out this review, the CHERG review guidelines were utilized (Walker, Fischer-Walker et al.). The CHERG guidelines are an extension of the Cochrane Collaboration and the Working Group for Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines for systematic reviews but focuses on assessing effects on child outcomes. Information gathered using the guidelines from CHERG is included in the Lives Saved Tool (LiST), which contains information on the effects of interventions on cause-specific child mortality parameters such as malnutrition.

Only studies that showed effects of women's groups on stillbirths, neonatal mortality and perinatal mortality were considered. Additionally, since developing countries account for most of the high stillbirth, neonatal and perinatal mortality burden, only women's groups in these countries were included. There were no language and time period restrictions for this systematic review. As much as possible, a search was done for studies utilizing randomized controlled trials and results from program evaluations were excluded from the systematic review. Other inclusion criteria are listed in Table 1.

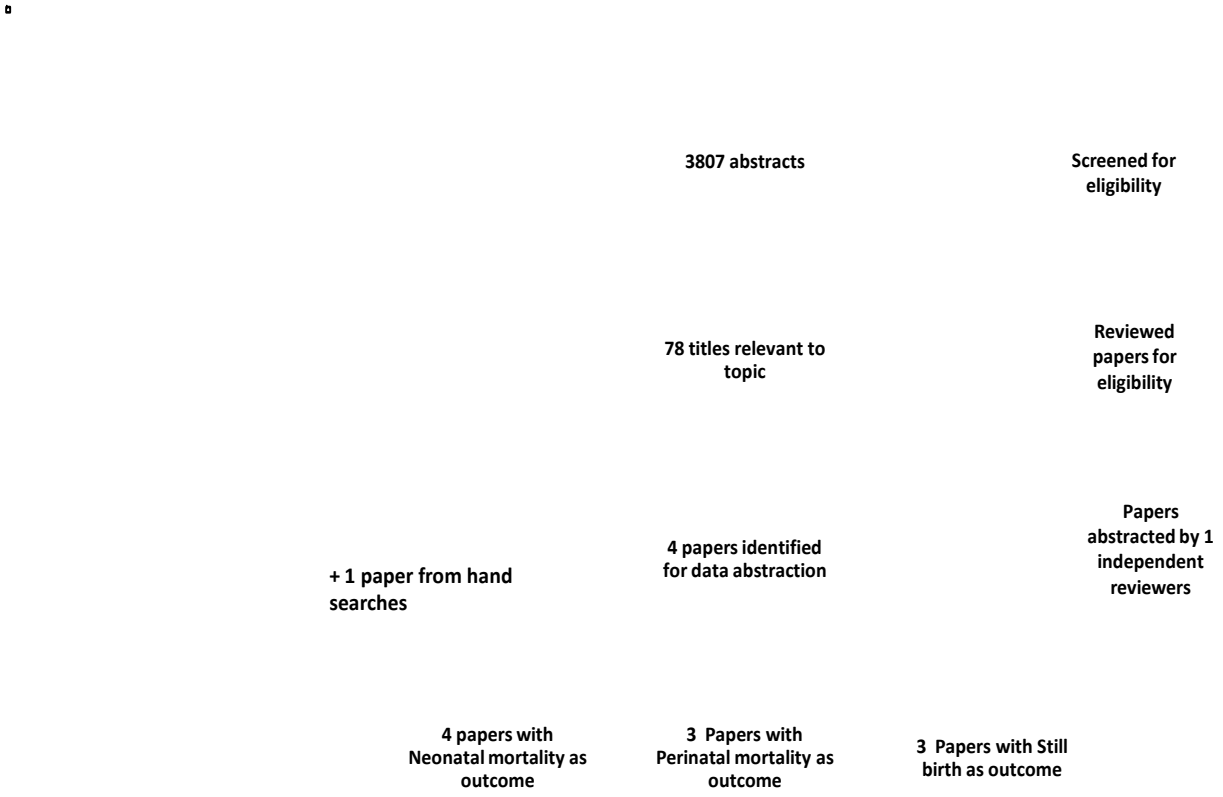
Table 1. Population, Intervention, Comparison and Outcome (PICO) table showing inclusion and/or exclusion criteria for selection of interventions into the review

Participants/ Population	Women of reproductive age mothers, pregnant women with or without children 0-23 months, mothers with children 0-23 months. For all cases, women must be between 15-49 years of age. Additionally, only interventions in developing countries are considered.
Intervention	Mother support group interventions, mother club interventions, women support group interventions, mother interchange group interventions, mothers' organization intervention, related to infant health outcomes. These interventions should include: • Original interventions, not reviews • a participatory approach or lecture style approach • meetings with women held at least once per month • a facilitator (either mothers or other health personnel) • a formal group of women working to change infant health outcomes and/or to achieve a particular aim related to infant health • Health education messages/ sessions Additionally, interventions that only include focus groups with a group of women will not be included in this review
Control Group	Mothers or women who did not participate in women's group/no intervention group, group receiving intervention other than mother or women's support.
Outcomes	Stillbirth rates, Neonatal mortality rates, perinatal mortality rates Stillbirth: fetal death after 28 weeks of gestation but before delivery of the baby's head Neonatal mortality: infants who have died at <= 28 days old or in the first month of life if number of days is not known. NMR is calculated as the number of deaths from any cause during the first year of life divided by the number of live births in the study population. Perinatal mortality: a stillbirth or death arising within 6 completed days Actual numerical results should have been gathered and stated in paper.

The search engines used were PubMed, Popline, Embase, Web of Science and the Cochrane Controlled Trials Register in the Cochrane Library. Combinations of the terms “mother support group”, “women support group”, “mother clubs”, mother interchange group”, “mother’s organization”, “perinatal mortality”, “neonatal mortality” and “stillbirth” were used to search these databases. A manual literature search was also done by utilizing the reference sections of articles to be abstracted. The search strategy for the review is summarized in Figure 3. The program Endnote was used to keep track of citations.

The titles of articles generated using the search terms were reviewed and articles fitting inclusion and exclusion criteria were abstracted for use in the review. Abstracted data was tabulated and stored in a Excel Database and information gathered was used to make judgements on study quality. In the case where the number of neonatal deaths was not stated explicitly in the Sylhet study, the number of deaths was calculated by hand. The formula for calculating NMR is: (number of neonatal deaths ÷ number of livebirths) X 1000. By making the number of neonatal deaths the subject of the formula, neonatal deaths was calculated using the formula (NMR X number of livebirths) ÷ 1000.

Figure 3. Search strategy and outcomes for CHERG review



The stipulations for determination of study quality were based on study design, loss to follow up, coverage of intervention, intention to treat analysis, adjustment for confounding and comparability of control and intervention groups at baseline. These stipulations were created on the basis of CHERG and GRADE guidelines (Balshem, Helfand et al. ; Walker, Fischer-Walker et al.). Scores of 'high', 'moderate', and 'low' were given to each trial based on these stipulations. A detailed explanation of these stipulations are presented in table 2.

Table 2. Showing stipulations for assessing the quality of individual studies (Balshem, Helfand et al. ; Walker, Fischer-Walker et al.).

Criteria	How Assessed
Coverage of intervention	• High-greater than 50% of target population participated in women's groups • Moderate- greater than 10% but less than 50% of target population participated in women's groups • Low- a very small proportion of target population participated in women's groups (1-10%)
Loss to follow-up	• High-low levels of loss to follow up (5% or below) • Moderate- above 5% but <=10% • Low- greater than 10%
Intention to treat analysis	• High- all randomised groups were analyzed in the groups to which they were allocated, those who migrated were analyzed according to their original group assignment • Moderate- Authors followed pre-stipulated assumptions for intention to treat analysis • Low- Authors did not follow pre-stipulated assumptions or randomised groups were not analyzed in the groups to which they were allocated and results from those who migrated was not included in final analysis.

CONTINUED FROM PREVIOUS PAGE

Criteria	How Assessed
Comparability of intervention and control groups at baseline	• High-Groups are similar based on all baseline characteristics or differences were adjusted for upon analysis • Moderate-Groups were similar on most baseline characteristics • Low-Groups were different on most baseline characteristics
Adjustment for confounding	• High- adjustment for clustering, stratification of data, loss to follow up, or baseline differences between intervention and control groups • Moderate- adjustment for clustering • Low- No adjustment for confounding
Study Design	• High- Randomized controlled trials with no major limitations • Moderate- Observational studies with a comparison group and no limitations • Low-Observational studies with no comparison group, no randomization and/or other limitations

A score ranging from “low” to “high” was assigned to each study based on the above criteria. If a study scored mostly “high” on all criteria, for example, the overall assessment for that study was “high”. Conversely, if the study received more “moderate” or “low scores”, the study was assessed as “moderate” or “low”. If the cumulative assessment for a study was split between two scores, the biases section was taken into consideration when deciding to either upgrade or downgrade a study’s assessment. Low scores downgraded the overall assessment for an

individual study and overall estimates of effect of women's groups was considered with and without a study designated as "low".

The overall quality of evidence in support of the effect of women's groups on neonatal mortality, perinatal mortality and stillbirth was assessed taking into consideration study design, limitations of studies, consistency of findings, generalizability to population of interest and intervention of interest and the effect estimates generated from the meta-analysis. The specific stipulations are explained below.

Table 3. Stipulations for assessing overall body of evidence for the effect of women's groups (Balshem, Helfand et al. ; Walker, Fischer-Walker et al.).

Criteria	How Assessed
Study Design	• High- Randomized controlled trials with no major limitations • Moderate- Observational studies with a comparison group and no limitations • Low-Observational studies with no comparison group, no randomization and/or other limitations
Consistency of findings	• High- if according to effect estimates the intervention favoured intervention or favoured controls, exclusively (similar direction of effect) • Low-if direction of effect is different across studies
Generalizability to population of interest and intervention of interest	• High- if the studies were representative of the population or intervention of interest • Low-if the studies were not representative

The meta-analysis generated risk ratios, odds ratios, associated confidence intervals, p-values and a test of heterogeneity value and gave information on estimates pertaining to individual women's group studies and overall estimates of effects of the studies combined. All "events" and "totals" were recorded in Review Manager 5.1 as crude values and what resulted after values were recorded in Review Manager 5.1 was a forest plot, that gave a graphical and numerical representation of results (Ried 2006). The graph in the forest plot consists of a line in the center called the line of no effect, which has a value of one when calculating risk ratios and odds ratios and a value of 0 when continuous outcome variables are calculated (Ried 2006). The weight of individual studies in the meta-analysis is represented by boxes, in which the bigger the box, the greater the weight of the study. Whiskers through the boxes give information on the width of the confidence interval and the longer the line, the wider the confidence interval is for a particular study (Ried 2006). The I^2 value in the meta-analysis tests the heterogeneity of studies included in the meta-analysis. An I^2 >= 75% indicates high levels of heterogeneity in studies and I^2 <=25% indicates homogeneity of studies. One reason for heterogeneity is differences in study design across trials. When there is evidence of heterogeneity of studies, a random effects meta-analysis is used while for homogeneous studies, a fixed effects model is used. The difference between the two models is in the weighting that is given to individual studies, with the random effects model giving more weight to small studies than the fixed effects model (Walker, Fischer-Walker et al. 2010).

The statistical evidence gathered from the meta-analysis was translated into recommendations for inclusion in LiST, with special consideration of the overall quality of evidence for the effect of the women's group interventions on the different health outcomes.

Using CHERG guidelines, if the overall effect estimate for trials that had effects on neonatal mortality rates, perinatal mortality rates or stillbirth had a corresponding p-value >0.10 then the women's group interventions were regarded as not having an effect on those outcomes. If the p-value was between 0.01 and 0.10, the women's group intervention had weak evidence of effect on the outcomes, if p was less than 0.01, there was an effect on the outcomes and if $p < 0.001$ then there was strong evidence that the interventions had an effect on the outcomes. Where there was evidence of effect and multiple RCTs was used to generate the overall effect estimate, the recommendation was that the women's group intervention should be included in LiST. If a single RCT was used and there is evidence of an effect of the intervention, the recommendation was that further research needed to be done. If the effect was weak, then careful consideration would have to be made before suggesting an inclusion of women's groups in LiST. Otherwise, the women's group intervention would not be recommended for inclusion in LiST.

This study was not required to be submitted to IRB.

RESULTS

78 relevant articles were identified, with only 6 articles remaining after abstract review. When the methods section of two of these six articles was further read, it was found that the intervention was a packaged one involving Lady health worker (LHW) and Dai training, creation of linkages between LHWs and Dais, and community mobilisation (which included monthly group sessions with women). LHWs and Dais in the control group did not receive additional training, linkages were not formed between Dais and LHWs and no group education sessions were held. It would therefore be difficult to isolate actual women's group effects from these two interventions. These two studies were part of the same intervention, with one being a pilot study and the other being the actual implemented study in Hala, Pakistan. These two articles were excluded from final analysis (Bhutta, Ahmed et al. 2008; Bhutta and Lassi 2010). The four remaining articles plus one article found from a manual search of references were included in this systematic review. The 73 (of a total of 78 articles) excluded articles and reasons for their exclusion from this review are shown in Appendix A.

Trial characteristics

The trials used in this review took place mainly in South Asia (Nepal, Bangladesh and India), except for one trial which took place in Bolivia. All trials targeted women of reproductive age who were likely to get pregnant during the study period. In the case of 4 of the trials; namely the Warmi project (O'Rourke, Howard-Grabman et al. 1998), the BADAS study (Azad, Barnett et al. 2010), the India study(Tripathy, Nair et al. 2010) and the Nepal study(Manandhar, Osrin et al.

2004), the community action cycle was utilized to assess neonatal issues and create strategies to address the issues. Most trials (4) also consisted of a health services strengthening component which was made available to both intervention and control groups. Meetings took place in study areas at least once a month. The levels of coverage for the interventions varied; with the India study having high coverage (Tripathy, Nair et al. 2010) and the Nepal (Manandhar, Osrin et al. 2004) study having moderate coverage (55% and 37% coverage respectively. The BADAS (Azad, Barnett et al. 2010) and Sylhet (Baqui, El-Arifeen et al. 2008) studies both had low coverage (2% and 9% coverage respectively) . Facilitators for the group meetings were typically female, literate and residents of the study area. The Sylhet study (Baqui, El-Arifeen et al. 2008), however utilized both female and male community mobilizers while the Warmi study (O'Rourke, Howard-Grabman et al. 1998) utilized study personnel to facilitate the women's group meetings. In terms of study design, four of the five trials utilized a cluster-randomised controlled design and there was no blinding or concealment of participants' allocation to groups. For these cluster randomised controlled trials too, analysis was based on intention to treat. The Warmi project (O'Rourke, Howard-Grabman et al. 1998) was unique in its quasi-experimental design and its lack of a comparison group to evaluate intervention effects. Detailed descriptions of all the studies are presented in Appendix B. To gather mortality data, 4 of the trials used verbal autopsy (Manandhar, Osrin et al. 2004; Baqui, El-Arifeen et al. 2008; Azad, Barnett et al. 2010; Tripathy, Nair et al. 2010) and 1 trial used a community registry (O'Rourke, Howard-Grabman et al. 1998).

The studies ranged in quality from 'low' to 'high' with the Nepal and India studies assessed as 'high', the Warmi project (O'Rourke, Howard-Grabman et al. 1998) assessed as 'low' and the Sylhet (Baqui, El-Arifeen et al. 2008) and BADAS (Azad, Barnett et al. 2010) studies

categorized as having ‘moderate’ study design and quality. The Warmi project (O'Rourke, Howard-Grabman et al. 1998) was assessed as low because it was quasi experimental in design, considered outcomes on the whole population, regardless of if they received the intervention, and in the analysis of results, there was no adjustment for confounding. Furthermore, the Warmi project (O'Rourke, Howard-Grabman et al. 1998) did not use a control group; for estimates of project success, perinatal mortality pre-intervention and post intervention was compared. The Nepal (Manandhar, Osrin et al. 2004) and India (Tripathy, Nair et al. 2010) studies had a strong study design and adjustment for confounding. Both studies had mostly “high” scores for the criteria used for assessment and had little or no biases. The BADAS study had a strong study design and so was initially graded as “ high” (Azad, Barnett et al. 2010). However, due to its large amount of limitations, low coverage and high loss to follow up, the score was downgraded to “moderate”. The Sylhet study (Baqui, El-Arifeen et al. 2008) had a strong study design, adjusted for confounding and the intervention and control groups were similar at baseline and for those reasons it was also initially given a score of high. Low coverage, high loss to follow up and other limitations caused the overall grade for this study to be downgraded to “moderate”. Results of quality assessments of individual studies are shown in Table 4.

Table 4. Quality Assessment of Individual Studies

Author, year	Design	Coverage	Comparability of groups at baseline	Loss to follow up	Intention to treat analysis	Adjustment for confounding?	Other biases	Overall Grade
Tripathy et al., 2010 (India)	High-Cluster RCT	High- 55% of newly pregnant women	Moderate-Baseline differences in household assets, maternal education, literacy and trial membership with the intervention group having worse outcomes.	High-<1% of women in intervention clusters and 2% of women in control clusters	Moderate-Yes but excluded mothers who migrated out of the region and their infants.	High-Yes	Intercluster migration of women	High
Manandhar et al, 2004 (Nepal)	High-Cluster RCT	Moderate-37% of newly pregnant women	Moderate-there was less poverty in intervention groups based on household asset scores and participant schooling	Moderate-5.4% in intervention clusters and 5% in control clusters	High-Yes, patients who started as residents of one cluster were considered as members of that cluster even if they moved	High-Yes	N/A	High
Azad et al, 2010 (BADAS)	High-Cluster RCT	Low- 9% of women of reproductive age, 2% of newly pregnant women	Moderate- A greater proportion of women in intervention areas had no education (50% in intervention areas versus 48% in control areas) and no household assets and were younger.	Low-16% in intervention clusters and 18% in control clusters	High-Yes, temporary and tea garden residents were included in the analysis for mortality outcomes	High-Yes	Low coverage, high loss to follow up, low retention of facilitators, inability of coordinators to support facilitators, flood in an intervention site, lack of support for women participating in groups from family members, other NGOs in area gave incentives for women to participate in their women's groups	Moderate

Author, year	Design	Coverage	Comparability of groups at baseline	Loss to follow up	Intention to treat analysis	Adjustment for confounding?	Other biases	Overall Grade
Baqui et al, 2008 (Sylhet)	High-Cluster RCT	Low to moderate- 6% to 36% of pregnant women attended meetings	High-all similar	Low-15% of women were lost to follow up	Yes but not reported how they went about this analysis	High-Yes	Contamination, less than 5% of births attended by community health workers	Moderate
O'Rourke et al, 1998 (Warmi project)	Low-Quasi-experimental	Not reported	N/A	N/A	N/A	Low-No	No control group, and data from whole population not just intervention population	Low

The effect of the interventions on neonatal health outcomes

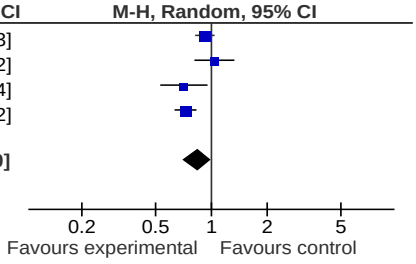
Four studies provided data on neonatal mortality, three studies provided information on perinatal mortality and three studies provided information on stillbirth.

Neonatal mortality

The I^2 value for the test of heterogeneity was 76%, indicating that there is strong evidence of heterogeneity in the studies as it relates to NMR. As a result a random effects model was used for the meta-analysis. The meta-analysis showed that overall there was a 16% reduction in neonatal mortality as a result of the women's groups but this result was not statistically significant (Table 5). Furthermore the confidence interval corresponding to the effect of all trials was wide and showed the true effect of women's group interventions is between a 0% to a 29% reduction in neonatal mortality.

Table 5. Random effects model of the relative risk of neonatal death in trials with women's group interventions

	Intervention		Control			Risk Ratio	Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**	**M-H, Random, 95% CI**
Azad et al, 2010	570	16926	656	17967	30.9%	0.92 [0.83, 1.03]	
Baqui et al, 2008	136	3009	125	2872	21.2%	1.04 [0.82, 1.32]	
Manandhar et al, 2004	76	2899	119	3226	18.1%	0.71 [0.54, 0.94]	
Tripathy et al., 2010	406	9469	531	8980	29.8%	0.73 [0.64, 0.82]	
Total (95% CI)		**32303**		**33045**	**100.0%**	**0.84 [0.71, 1.00]**	
Total events	1188		1431				
Heterogeneity: Tau² = 0.02; Chi² = 12.40, df = 3 (P = 0.006); I² = 76%							
Test for overall effect: Z = 1.98 (P = 0.05)							



Results of the meta-analysis were inconsistent when individual trials were considered. The women's group intervention led to statistically significant reductions in neonatal mortality only in Nepal (Manandhar, Osrin et al. 2004) and India (Tripathy, Nair et al. 2010). However, the

confidence interval for the Nepal study was wide (95% CI: 0.54-0.94) and reductions in deaths as a result of the intervention ranged from 6% to 46%. The results from the Nepal study are imprecise and this is likely owing to the small amount of births in that study. As a result, the Nepal study is 'low-powered' and provides less information than the other studies on the effect of women's groups. The Sylhet study (Baqui, El-Arifeen et al. 2008) data was heavily weighted in the meta-analysis (21.2%), but with its low coverage and high losses to follow up, it's large effect on overall results is highly problematic. The study did not show an effect of the women's group intervention on neonatal mortality (RR= 1.04; 95% CI: 0.82-1.32). The BADAS study too was highly biased due to high losses to follow up and a 2% coverage. No effect of the intervention was seen in this study. Overall, the women's group intervention had no significant effect on NMR (RR=0.93, 95% CI 0.75-1.14).

Perinatal mortality

Studies identified as having effects on perinatal mortality were highly heterogeneous (I^2>75%, p<0.00001) and as with modelling for the neonatal mortality outcome, a random effect model was used to compare study effects on perinatal mortality (Table 6). The meta-analysis showed that overall there was a 27% reduction in perinatal mortality as a result of the women's group intervention and that result was statistically significant. The overall RR and corresponding 95% CI suggested that the women's group intervention reduced perinatal mortality (RR=0.73, 95% CI: 0.55-0.97). The overall meta-analysis is questionable due to limitations in both the Warmi project (O'Rourke, Howard-Grabman et al. 1998) and BADAS (Azad, Barnett et al. 2010)studies.

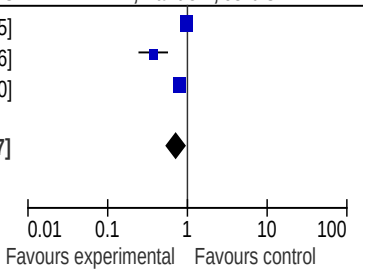
The Warmi project in Bolivia (O'Rourke, Howard-Grabman et al. 1998) indicated the highest reduction in perinatal mortality, followed by the India study (Tripathy, Nair et al. 2010). However, this project used data gathered from a community registry and included mortality results from both people who participated in the intervention and those who did not. A pre-post intervention comparison was used to draw conclusions about project effects (O'Rourke, Howard-Grabman et al. 1998) . Biases could have been introduced because improvements that were seen could have been due to other factors in the study area outside of the women's groups. This is difficult to determine in the absence of a control group. The Warmi study (O'Rourke, Howard-Grabman et al. 1998) was not sufficiently powered to make determinations of effect (due to the small amount of births analyzed) and thus results are not reliable. The BADAS study (Azad, Barnett et al. 2010) indicates that the intervention had no effect on perinatal mortality and was heavily weighted in the analysis due to its large sample size. Again this is problematic due to the high losses to follow up and low coverage utilized in that study.

Table 6. Random effects model of the relative risk of perinatal death in trials with women's group interventions

	Intervention		Control/Intervention+			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
Azad et al, 2010	1048	17514	1146	18599	39.3%	0.97 [0.90, 1.05]	
O'Rourke et al, 1998	31	708	75	639	22.3%	0.37 [0.25, 0.56]	
Tripathy et al., 2010	560	9770	660	9260	38.3%	0.80 [0.72, 0.90]	
Total (95% CI)		**27992**		**28498**	**100.0%**	**0.73 [0.55, 0.97]**	
Total events	1639		1881				

Heterogeneity: Tau² = 0.05; Chi² = 25.50, df = 2 (P < 0.00001); I² = 92%

Test for overall effect: Z = 2.17 (P = 0.03)

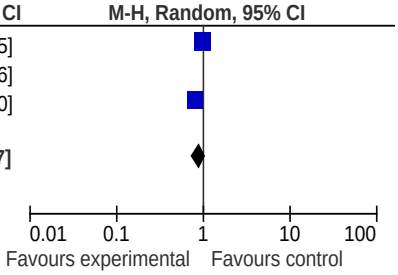


Owing to the Warmi project being previously assessed as “low”, overall estimates for effect on perinatal mortality were also considered in the absence of this study (Table 7). When the Warmi study was given no weight in the meta-analysis, women’s groups showed only a slight effect on perinatal mortality and this result was not statistically significant. This suggests that much more research evidence is necessary to make final conclusions about women’s group effects on perinatal mortality.

Table 7. Random effects model of the relative risk of perinatal death for trials with women’s groups interventions (in the absence of the Warmi project trial)

	Intervention		Control/Intervention+			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
Azad et al, 2010	1048	17514	1146	18599	51.9%	0.97 [0.90, 1.05]	
O’Rourke et al, 1998	31	708	75	639	0.0%	0.37 [0.25, 0.56]	
Tripathy et al., 2010	560	9770	660	9260	48.1%	0.80 [0.72, 0.90]	
Total (95% CI)		**27284**		**27859**	**100.0%**	**0.89 [0.74, 1.07]**	
Total events	1608		1806				

Heterogeneity: Tau² = 0.02; Chi² = 7.40, df = 1 (P = 0.007); I² = 86%
Test for overall effect: Z = 1.27 (P = 0.20)



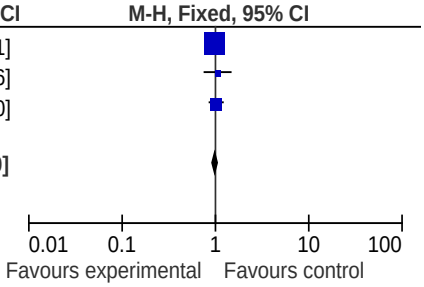
Stillbirth Rate

The studies utilized for analyzing stillbirth effects exhibited low heterogeneity (I^2=0%) and therefore a fixed effects model was used (Table 8). For all studies, the women’s group intervention had no effect on stillbirth rate (OR=1.00, 95% CI: 0.92-1.10). The BADAS study (Azad, Barnett et al. 2010) was heavily weighted in calculation of overall effects.

Table 8. Fixed effects model of the odds of stillbirth in trials with women's group interventions

Study or Subgroup	Intervention Events	Intervention Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Azad et al, 2010	588	17514	632	18599	62.9%	0.99 [0.88, 1.11]
Manandhar et al, 2004	73	2972	77	3303	7.6%	1.05 [0.76, 1.46]
Tripathy et al., 2010	301	9770	280	9260	29.6%	1.02 [0.86, 1.20]
Total (95% CI)		**30256**		**31162**	**100.0%**	**1.00 [0.92, 1.10]**
Total events	962		989			

Heterogeneity: Chi² = 0.20, df = 2 (P = 0.90); I² = 0%
Test for overall effect: Z = 0.05 (P = 0.96)



Based on statistical evidence from the meta-analysis, limitations of studies, consistency, study design and the generalizability of the studies, the quality of evidence for the effect of women's groups on neonatal mortality is moderate, for perinatal mortality is moderate and for stillbirth rates is high (Table 8).

Quality assessment of the body of evidence

The overall assessment of studies (Manandhar, Osrin et al. 2004; Baqui, El-Arifeen et al. 2008; Azad, Barnett et al. 2010; Tripathy, Nair et al. 2010) showing effects on neonatal mortality were initially graded as "high" due to all studies using a cluster-RCT design. The score was downgraded to moderate due to low consistency of results; two studies (Manandhar, Osrin et al. 2004; Tripathy, Nair et al. 2010) showed an effect on neonatal mortality, one study showed no effect (Baqui, El-Arifeen et al. 2008) and another study (Azad, Barnett et al. 2010) showed results that were not statistically significant.

The overall assessment of studies showing effects on peinatal mortality was initially graded as “moderate”, then was upgraded to “high” due to consistency in the use of the participatory approach and there South Asian location (O'Rourke, Howard-Grabman et al. 1998; Azad, Barnett et al. 2010; Tripathy, Nair et al. 2010). The quality of evidence for effects on perinatal mortality were downgraded back to “moderate” due to inconsistency of findings both in the presence and absence of the Warmi project (O'Rourke, Howard-Grabman et al. 1998).

Studies showing effects on stillbirths were consistent in findings, and generalizability (O'Rourke, Howard-Grabman et al. 1998; Azad, Barnett et al. 2010; Tripathy, Nair et al. 2010).

Translating statistical evidence into recommendations for inclusion in LiST

There was weak or no evidence of effect of women’s group interventions on neonatal mortality and stillbirth rates and therefore there is insufficient evidence to recommend its inclusion unless additional evidence is available from other sources. There is weak evidence of effect of the women’s group intervention on perinatal mortality rates and thus careful consideration and judgement is required before recommendation for its inclusion.

Table 9. Quality assessment of trials identified through systematic review of the effect of women's groups on infant mortality

Quality Assessment							
				Directness		**Summary of Findings**	
No. of studies	**Design**	**Limitations**	**Consistency**	**Generalizability to population of interest**	**Generalizability to intervention of interest**	**No. of participants at risk (exposed group)**	**Effect estimate**
Neonatal mortality-Overall quality of evidence: Moderate							
4	High-Cluster RCT	Two of the studies had high losses to follow up. Mortality rates were based on verbal autopsy which depends on recall; this may have introduced some bias.	Low-2 studies showed a significant reduction in neonatal mortality rate. 1 study showed a slight reduction in neonatal mortality because of the intervention but the result was not significant and another study showed no effect.	High-All studies were in South Asia and effects may be generalizable to women in rural areas of that setting. All interventions occurred in rural settings with poor access to healthcare.	Low-All studies except one utilized a participatory action cycle therefore results are generizable to women's group interventions utilizing a participatory approach, that occur in resource poor, rural settings with poor access to health services.	2580	RR= 0.93, 95% CI: 0.75-1.14
Perinatal mortality-Overall quality of evidence: Moderate							
3	Moderate-2 Cluster RCT and 1 Quasi-Experimental	1 study had a weak study design and no control group. Other studies had low coverage and high losses to follow-up.	Low- Two studies indicated a significant reduction in perinatal mortality rates as a result of the intervention, with the study with the weakest design indicating the largest reduction in perinatal mortality. One study indicated no effect of the intervention	High-Two of the studies were in South Asia and one was in South America. All studies occurred in rural areas. Effects may be generalizable to that setting.	Low-3 studies utilized a participatory women's group strategy.	1639 with Warmi project (O'Rourke, Howard-Grabman et al. 1998) and 1608 without the Warmi project (O'Rourke, Howard-Grabman et al. 1998)	With Warmi project(O'Rourke, Howard-Grabman et al. 1998), RR=0.73, 95% CI: 0.55-0.97 Without the Warmi project(O'Rourke, Howard-Grabman et al. 1998), RR=0.89, 95% CI: 0.74-1.07

Quality Assessment Continued							
				Directness		Summary of Findings	
No. of studies	**Design**	**Limitations**	**Consistency**	**Generalizability to population of interest**	**Generalizability to intervention of interest**	**No. of participants at risk (exposed group)**	**Effect estimate**
Stillbirth-Overall quality of Evidence: High							
3	High-Cluster RCT	Studies had loss to follow up, low coverage, and differences in control and intervention groups at baseline.	High-For all studies, the intervention did not have an effect on stillbirth rate.	High-All studies were in South Asia and in rural, resource poor settings and results maybe generalizable to that setting	High-For robust and weak studies alike, the women's group intervention had no effect on stillbirth rates. One may be able to conclude then that this intervention should not be utilized to lower stillbirth rates.	962	OR=1.00, 95% CI: 0.92-1.10

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

The five studies utilized for the systematic review showed that there was no overall effect of women's groups on neonatal mortality and stillbirth rates (RR=0.93, 95% CI 0.75-1.14; OR=1.00, 95% CI: 0.92-1.10 respectively). Results from the meta-analysis showed a small effect of women's groups on perinatal mortality (RR=0.73, 95% CI: 0.55-0.97). However, when the Warmi project (O'Rourke, Howard-Grabman et al. 1998) was removed from this analysis the association was weaker and was not statistically significant (RR=0.89, 95% CI: 0.74-1.07).

The quality of the evidence supporting an effect of women's group interventions on perinatal and neonatal mortality was "moderate" while for stillbirth the quality of evidence was "high". Individual studies ranged in quality from "low" to "high" with studies in Nepal (Manandhar, Osrin et al. 2004) and India (Tripathy, Nair et al. 2010) assessed as "high" and two studies in Bangladesh assessed as "moderate". The quality of evidence for the Warmi project (O'Rourke, Howard-Grabman et al. 1998), was assessed as "low".

The lack of overall effect of women's groups on stillbirths, perinatal and neonatal mortality could be due to the following factors:

High Workload

The fact that facilitators and enumerators were responsible for a larger cohort than other trials in the two Bangladesh studies could have influenced the results in those areas (Baqui, El-Arifeen et al. 2008; Azad, Barnett et al. 2010). Community health workers for the Sylhet study (Baqui, El-Arifeen et al. 2008) were responsible for going to the houses of women every two months to

identify pregnancies. However, they were only able to attend less than 5% of births because of their high work load. For the BADAS study (Azad, Barnett et al. 2010), there was difficulty in the retention of facilitators and supervisors to lead women's groups. This led to disruptions in meetings which may have compromised the quality and dose of the women's group intervention for the women.

Improper use of intention to treat analysis

For the India study (Tripathy, Nair et al. 2010), the authors noted in the article that analysis was by intention to treat but excluded mothers who migrated out of the study area and their infants. Intention to treat analysis is usually considered in terms of analyzing what one randomizes. By randomizing clusters to groups, each cluster is given equal likelihood of being allocated to either the intervention or control group. By not analyzing what one randomizes, one can bias results if there were major differences between those who migrated out of the study area and those who remained.

A focus on results from RCTs

RCTs give probability statements about the impact of an intervention on particular outcome (Victora, Habicht et al. 2004). In the absence of researchers, traditional birth attendants and other personnel might not readily see an incentive for consistently tracking births and deaths in their communities and facilitators may be less apt to sustain women's group meetings. The conclusions that are made from women's groups that did show effects are based on the

assumption that proper surveillance took place, that women consistently attended meetings, and that health services were strengthened (Victora, Habicht et al. 2004).

Verbal autopsy

In the case of the four trials that utilized verbal autopsy, there could be recall bias, underreporting or over-reporting of data, which would have significantly biased results. However, in both the India (Tripathy, Nair et al. 2010) and BADAS (Azad, Barnett et al. 2010) studies a key informant initially obtained information on births and deaths and an interviewer verified the births and deaths with the mother and the family of the infant who died. Furthermore, in the case of the BADAS study (Azad, Barnett et al. 2010), the key informant was paid an incentive for accurate reporting. In the four studies too, interviews were done very close to the birth or death of a child which reduces the likelihood of biases due to recall (most within 6 weeks after a birth). Additionally, verbal autopsy was used both in intervention and control groups so any potential biases would have likely affected both groups similarly.

Inclusion of the Sylhet study

In articles discussing women's group effects, the Sylhet study was not discussed in terms of women's group interventions. This raised concerns about the validity of including the Sylhet study as a standard women's group intervention. If in fact not a true women's group intervention, its inclusion in the meta-analysis could have been an under-estimation of the effect of women's groups. The intervention did not use a participatory approach but involved transmission of BCC

messages with pregnant women and female family members in groups, therefore qualifying it to be included in this systematic review.

Effects on Behaviour change

In the Sylhet study, there were improvements in antenatal checkups (a 12% improvement in arm with women's groups versus a 3% increase in the control group) and newborn care practices, but this did not translate to reductions in neonatal mortality (Baqui, El-Arifeen et al. 2008). This could have been due to one of two things. Firstly, the collection of data on practices was based on household surveys (Baqui, El-Arifeen et al. 2008). It is possible that women either reported what they thought the researcher wanted to hear or there was recall bias. Secondly, improvements in those two indicators were seen both in the intervention and control groups which indicates that there was intervention contamination, with not only the intervention group benefiting from behavioural messages on birth and newborn preparedness but also the control group (Baqui, El-Arifeen et al. 2008). On the pathway from intervention to health outcome, improvements in antenatal checkups and newborn care practices should have led to reductions in neonatal mortality in this context since the behaviours that were changed were relevant to the major causes of death in Sylhet (Kumar, Kumar et al. 2010) .

In Nepal, where the main causes of neonatal death were complications of preterm birth, birth asphyxia and infection, the intervention led to improvements in uptake of antenatal care, improved in deliveries at a health facility, improvements in the use of clean home delivery kits and improvements in the washing of hands by birth attendants (Manandhar, Osrin et al. 2004).

These improvements are in alignment with changes that would have been needed to reduce disease burden and ultimately death in that setting (Manandhar, Osrin et al. 2004).

For the BADAS study (Azad, Barnett et al. 2010), the lack of improvements in health care seeking behaviours and home care practices most likely led to lack of effect of the intervention on neonatal and perinatal mortality(Azad, Barnett et al. 2010). The lack of effect on behaviours is likely due to low coverage, low retention of facilitators, the flood in the intervention site and lack of support of women participating in groups by their family members. Low coverage meant not a high amount of people would have received the intervention and the behaviour changes messages. The low retention of facilitators and the lack of support for women participating in the groups also likely lowered participants' motivation to participate in these groups and to change their behaviours(Azad, Barnett et al. 2010).

Too few studies

Few studies involved women's group effects on stillbirth. For all three studies that were found as a result of the systematic review, there was no effect of the women's group intervention on stillbirth rates. However, it is known that the prevention of stillbirth is complex. Complications from delivery, Malaria, pre-eclampsia, infection, placental dysfunction, poor nutrition, lack of antental care and a host of other factors preclude ones risk for stillbirth (McClure, Nalubamba-Phiri et al. 2006). One's risk for stillbirth can be reduced if proper screening and medical services are sought before delivery. At delivery, the quality of care received by the pregnant woman is also important in preventing stillbirth. Education received at women's group meetings

can improve ones careseeking behaviour but pregnant women still need to have prenatal checkups and a skilled birth attendant needs to be present at the time of delivery. This could explain why all studies showed no effect of the women's group intervention on stillbirth. Notwithstanding, in a cluster randomized controlled trial that involved training of traditional birth attendants in Pakistan, there was a 31% reduction in stillbirth in the intervention group compared to the control group (adjusted OR 0.69, 95% CI:0.57-0.83) (Jokhio, Winter et al. 2005). Studies in Zimbabwe and Latin America showed that risk of stillbirths was less likely among women who received prenatal care (adjusted RR 2.54; 95%CI: 2.19-2.94 and adjusted RR 4.26; 95% CI:3.84-4.71 respectively)(Conde-Agudelo, Belizan et al. 2000; Feresu, Harlow et al. 2005).

Lack of variability in location of studies

A major limitation of this systematic review is the scarcity of trials with effects of women's groups on neonatal outcomes. Of those that were available, the quality of evidence was not consistent. The intervention was not successful in the two Bangladesh sites(Baqui, El-Arifeen et al. 2008; Azad, Barnett et al. 2010), which could be due to the limitations already highlighted, or could point to the fact that women's groups are not as valid for that setting. In the case of the BADAS study (Azad, Barnett et al. 2010) for example, it was noted that family members of some of the women did not support the women participating in the groups. This, along with other limitations might have significantly doomed the intervention in that setting to failure. In the Sylhet trial (Baqui, El-Arifeen et al. 2008), the intervention with home visits seemed to be much more valuable at reducing neonatal outcomes.

Four of the five studies took place in South Asia. Future research needs to assess how findings from South Asia can be translated to Sub-Saharan Africa, a region that also has a high burden of neonatal mortality. The MaiMwana trial in Malawi (2009; Rosato 2010), utilizing a participatory approach and women's groups to solve neonatal issues is a step in that direction. Results from that trial, however, are not yet available. Additionally, results from a study done in Mumbai are also forthcoming (2009).

Additionally, on a large scale basis, more trials evaluating the effectiveness of women's group interventions on stillbirth, neonatal and perinatal mortality need to be done so more valid conclusions can be made about the effectiveness of women's groups. Other reviews and articles that discuss the effect of the women's group intervention on neonatal mortality also note effects of the interventions in India (Tripathy, Nair et al. 2010) and Nepal (Manandhar, Osrin et al. 2004) but no effect for the BADAS study (2009; Bhutta and Lassi 2010; Osrin and Prost 2010; UCL 2010; Wellcome Trust 2010).

From the meta-analysis, it is clear that much more research needs to be done to detect if delivering interventions through women's groups will be an effective intervention strategy. Based on the small amount of studies used for each outcome, it is apparent that as it now stands, the women's group approach may not be the best intervention for reducing neonatal mortality, perinatal mortality and stillbirth rates. The test for overall effect corroborates this finding with a $p=0.20$ for perinatal mortality, a $p=0.96$ for stillbirth rate and $p=0.48$ for neonatal mortality rate.

Although, with limitations, the systematic review is a great first step in highlighting what may work in terms of women's group and what doesn't. It is clear from the successes and failures of the reviewed trials that women's group intervention require large enough population coverage to have some level of an effect. As Azad et al noted, 30-50% of newly pregnant women and approximately 1 per 450-750 population coverage might be required for meaningful effects to be seen. In the BADAS study (Azad, Barnett et al. 2010), 2% of newly pregnant women took part in groups while the Nepal (Manandhar, Osrin et al. 2004) and India (Tripathy, Nair et al. 2010) studies had much larger coverage (55% and 37% respectively). Additionally, the systematic review shows that on some level, the participatory approach is superior to approaches where BCC messages are disseminated to women if one compares the Sylhet study (Baqui, El-Arifeen et al. 2008) to the four other studies(O'Rourke, Howard-Grabman et al. 1998; Manandhar, Osrin et al. 2004; Azad, Barnett et al. 2010; Tripathy, Nair et al. 2010). Other studies have also noted the positive impact of participatory approaches compared to standard approaches in health promotion (Chambers 1994; Rifkin, Lewando-Hundt et al. 2000; Litsios 2004; Malhotra, Mathur et al. 2005; Rosato, Laverack et al. 2008).

IMPLICATIONS/RECOMMENDATIONS

Implications for Public Health Practice

The results of this systematic review and meta-analysis indicate that women's support group do not have an effect on neonatal mortality, perinatal mortality and stillbirths. This evidence is, however, based on a small number of cluster RCTs and one quasi-experimental study and results

are based on data from South Asia. More evidence based research needs to be done to ascertain the effect of women's groups on neonatal and perinatal mortality. Additionally, research should be done on the effect of these women's groups in settings outside of South Asia such as Sub-Saharan Africa.

Recommendations

In light of the findings from the systematic review and meta-analysis, it is recommended that:

- More research is done on the effect of women's group interventions on neonatal and perinatal mortality in developing countries as a whole, and in Sub-Saharan Africa in particular. Trials found by meta-analysis were largely based in South Asia (Manandhar, Osrin et al. 2004; Baqui, El-Arifeen et al. 2008; Azad, Barnett et al. 2010; Tripathy, Nair et al. 2010).
- Robust study designs such as RCTs or observational studies that use comparison groups should be used to quantify the effects of women's groups. Inclusion of the quasi-experimental trial, the Warmi project (O'Rourke, Howard-Grabman et al. 1998) was problematic because results were based on pre-post intervention comparisons and there were no control groups. With pre-post intervention comparisons and no control group, one cannot definitively say that the effects that were seen were solely due to the intervention; improvements could merely have occurred by chance.
- Evaluation studies should be used to explain the route by which women's groups are able to impact health outcomes directly. If the mechanisms are known by which certain

behaviours translate to reductions in outcomes such as neonatal and perinatal mortality, then key behaviours can be tailored within women's groups to address leading causes of neonatal and perinatal death.

- Women's group interventions need to be implemented at scale and cover atleast 30-50% of newly pregnant women (Bhutta and Lassi 2010). Studies in Nepal (Manandhar, Osrin et al. 2004) and India (Tripathy, Nair et al. 2010) that had moderate to high coverage showed significant effects on neonatal mortality and perinatal mortality.
- Key players in making the intervention a success (such as facilitators) should be supported and not given heavy workloads; this will not only affect the motivation of the facilitators to participate in these groups but also the women as well. This served as a limitation in the BADAS study (Azad, Barnett et al. 2010).
- Behavioural messages transmitted through the women's groups should be pertinent to major causes of disease in the study area and should consider historical and social context factors that might compromise the transmission of these messages and the ability of these messages to lead to behaviour change among women. For example, major causes of neonatal and perinatal mortality in the Nepal study (Manandhar, Osrin et al. 2004) were complications of birth, infections and birth asphyxia. Behavioural messages through women's groups were created that addressed these leading causes of neonatal and perinatal deaths. Tailored behavioural messages contributed to changes in behaviour and ultimately reductions in neonatal and perinatal mortality (Manandhar, Osrin et al. 2004).
- Efforts should be made to increase interest in these groups by major decision makers such as policy makers and stakeholders on a large scale and husbands in the case of patriarchal

societies. For example, in the BADAS study (Azad, Barnett et al. 2010), there was not support from the family of women to participate in the women's groups.

- As much as possible women's groups should be participatory. Evidence exists in the literature about the effectiveness of participatory approaches.
- Verbal autopsies should be verified by multiple sources such as two surveillance teams or with the use of medical records.

EXPERIENCE FROM THE FIELD: WOMEN'S SELF HELP GROUPS IN CALHUITZ, GUATEMALA

Calhuitz, is a mountainous, remote community found in Northern Guatemala in the Department of Huehuetenango, in the district of San Sebastian Coatán. It is characterized by frequent rainfalls and poor quality roads making it difficult for this community to be reached by organizations that want to aid in its development (economically, or otherwise). Because of its geographical location and the conditions of the roads, too, it is hard for people to leave the community to obtain medical care, the nearest hospital 5 hours away from Calhuitz. In its place, the Casa Materna provides health services to the community. The two nurses at the Casa Materna as well as other Casa Materna staff, perform deliveries, make house visits to women in the area (usually educating them on proper breastfeeding techniques, family planning etc.), organize and provide health education workshops and provide other health services.

The work of the Casa Materna, Curamericas and Global H.E.E.D is limited by the prevalence of teenage pregnancy. A common belief in Calhuitz is that women should have children by the age of 18 years old; if a girl doesn't have a child by the age of 18, she is considered too old after that to be eligible for marriage. Women who have children at an early age are not emotionally, mentally and physically prepared to take proper care of their child. This serves as a major barrier for improvements in child survival. As of 2010, 1364 people lived in Calhuitz; 661 females and 703 males. Most of the people in Calhuitz speak Chuj and only a few individuals are also able to speak Spanish (2010). To ensure that language is not a barrier in program implementation, staff from the Casa Materna and comunicadoras fluent in Chuj are utilized to transmit the health education messages.

The Intervention

The women's group intervention in Calhuitz, Guatemala follows the framework of a larger child survival project that was implemented in the Department of Huehuetenango between October 1, 2002 and September 30, 2007 by Curamericas Guatemala (Beracochea 2007) . The approach utilizes a Census-based, Impact oriented (CBIO) model and Care group model. Through the CBIO model, women and children are identified in the community, a map is made of the community and census data on the whole community is gathered (Beracochea 2007). The Care group model consists of health educators who train health communicators (Comunicadoras en Salud) about key health messages related to nutrition, maternal and newborn care, among other topics (Beracochea 2007). These comunicadoras in turn hold monthly group meetings with

women from their community (grupos de autocuidado) in which they disseminate the key health messages.

From June to August 2010, two nurses and one health educator from the Casa Materna and one health educator from SIAS led the women's group meetings in Calhuitz. SIAS (Integrated System of Health Care) is a program implemented by the Guatemalan government, USAID and other donors. Members of SIAS collaborate with the local clinic staff to deliver services to the women. The SIAS team consists of a health educator, a health facilitator, an information technology specialist and a nurse.

The women's group meetings were held twice per month. Each month, one session centered around nutrition through home based workshops (taller hogareños) and the other monthly session centered around other topics related to child health such as danger signs during pregnancy and diarrhea prevention (taller educativo). During the month of July, the focus of the health eduction was on hygiene and specifically proper handwashing. At the beginning of these meetings, women were asked to answer questions about their hygiene practices. The intervention was implemented at the sector level. Sectors can be thought of us as sub-communities within the larger community. There are four sectors within Calhuitz and the houses in sector one, for example, are close to each other but far from the houses in sector four. By addressing the issue of child mortality and morbidity at the sector level, it is ensured that the individual needs of women of each "sub-community" are met. Within each sector, three female leaders are chosen to serve as health communicators (comunicadoras en salud) who educate other mothers from their sector

informally on how to improve the health of their children. These women, in general, are able to speak Spanish and the local language, chuj, are able to read and write and their children are healthy. They serve as role models for the other mothers in the community and are best able to advise them on how to properly care for their children. In a patriarchal society like Calhuitz, where women are discriminated against in terms of health and education, having women serve as leaders will help to make the women feel empowered.

Findings

During the summer months (June to August 2010), 18 women from sector 1, 23 women from sector 2, 21 women from sector 3 and 18 women from sector 3 attended the meetings for a total of 80 women. According to 2010 census data there were 340 women of childbearing age living in Calhuitz. Therefore, the self help groups covered 23.5% of women of childbearing age in Calhuitz. However, it is important to note that the intervention was targeted to women with children under the age of five and so women who fell outside of this criteria may not have attended meetings. Notwithstanding, a total of 105 children under the age of five years old were served by the intervention.

For all sectors, most of the women were between 15 and 49 except for Sector 1 with one woman that was 48. The average age for women in Sector 1 was 31, for Sector 2 was 29, for Sector 3 was 27 and for sector 4 was 24.

In sector 1, women appeared reluctant/ shy about discussing their hygiene practices. Additionally, the women found it difficult to understand the questions. Eventually, all women

responded that they only washed their hands before cooking, they washed the hands of their children before they eat and all women reported that they used soap to wash their hands. They noted also that they did not brush their teeth or their children's teeth on a regular basis. They only time that they did brush their teeth and/or the teeth of their children was when they were able to afford toothpaste. All women reported using a towel to wash their hands, that they had electricity, used soap to clean their kitchen and wash their dishes, that they covered their food if they did not eat it immediately and that they showered three times per week. These results may or may not be representative of the opinions of individual women in Sector 1 and the results may have been skewed by "group think". The Global H.E.E.D. personnel had revised the oral survey questions for Sector 2. The results for sector 2 are shown below.

Table 10. Showing responses of Sector 2 women to oral survey questions

Prompt (N=10)	Number who answered yes to prompt
1. I wash my hands:	
Before Cooking	10
Before feeding their children	6
After using the bathroom	10
After they change their children's diaper	10
2. I wash my children's hands:	
After they use the bathroom	10
Before they eat	10
After they eat	0
3. I wash my hand with:	
Soap (specifically tex or gallo brands)	10
Nothing	0
Detergent	0
Shampoo	0
Towel	0
4. Do you have a latrine?	
Yes	10
5. How many times do you brush your teeth per day?	
1 time	5
2 times	2
3 times	1
4 times	2
6. What do you brush your teeth with?	
Toothpaste	10

Preliminary anthropometric data taken on children participating in the taller hogareños showed the dire need for this intervention in Calhuitz (Table 11). Anthropometric data was only available for 70 of the 105 children who the intervention served (67% of children). All the children ranged from 0-60 months. 21.1% of the children in the Sector 1 group were underweight, 78.9% were

stunted and none of the children were wasted. In Sector 2, 46.7% of the children were underweight and 92.9% were stunted. Prevalence of stunting and wasting were lower in Sector 3 with 13.6% of children underweight and 71.4% of children stunted. Additionally, 3.7% of children in Sector 3 were wasted. Results were comparable in Sector 4 with 14.3% of children underweight and 83.3% of children stunted.

These results indicate that among children who are participants in the self help groups, there is a high severity of underweight in Sector 1, a very high severity in sector 2 and medium severity of underweight in Sectors 3 and 4. In all sectors, there was a high severity of stunting. In sector 3, there was a low severity of wasting. These results indicate that there is a shortage of adequate nutrients among children in these groups and children in this area run the risk of reduced productivity in the future, inability to resist infections, inadequate growth and reduced mental capacity if these trends continue. These results indicate a great need for women to improve what they are feeding to their children, a sentiment shared by a Casa Materna staff member who noted, “sometimes we hear mothers say things like, my son doesn’t want to eat carrots because he doesn’t like it; therefore we need to create variety in the way we prepare foods so we can improve their weight status, know about pneumonia and diarrhea prevention as well as hygiene.”

Table 11. Prevalence of Malnutrition among children who participated in self help groups (2010)

Sector ***(N=70)***	**n**	**Sex**	**Underweight* (%)**	**Stunting** (%)**	**Wasting*** (%)**
1	7	F	28.6	100	0
	12	M	16.7	66.7	0
	19	T	21.1	78.9	0
2	9	F	55.6	100	0
	6	M	33.3	83.3	0
	15	T	46.7	92.9	0
3	10	F	16.7	66.7	6.3
	12	M	10	77.8	0
		T	13.6	71.4	3.7
4	6	F	0	66.7	0
	8	M	25	100	0
	14	T	14.3	83.3	0

*weight for age <-2 SD **height for age <-2 SD ***Weight for height <-2 SD ((De Onis and Blossner 1997)

F-Female M-Male T-Total

As indicated from the high malnutrition rates among children in the self help groups, there is a huge need in Calhuitz, for an intervention that improves the nutritional status of children. Effects of Growth monitoring over time will give an idea of the impact this intervention is having on malnutrition rates.

In conducting self help groups in Calhuitz, standard teaching methods were used to impress upon the women the importance of certain foods in the diet of their children as well as in teaching them about topics such as hygiene. Women actively participated in the intervention by preparing foods, demonstrating proper handwashing techniques and serving as leaders of the group. However, there is still more that can be done to integrate women in creating strategies to tackle the issue of malnutrition in Calhuitz, since the current strategy is focused on knowledge flowing from the Casa Materna staff without the input of the women. As seen from the systematic review and metanalysis and as noted elsewhere, participatory approaches do work. It is therefore recommended that more is done to integrate the women of Calhuitz in all stages of the decision making about the health of their children.

Additionally, the following recommendations are also offered:

- The resources available at the Casa Materna need to be strengthened so that changes in behaviour can be linked to available health care services. Specifically, the most pressing need the Casa Materna has is that they are in dire need of an

ambulance to transport women and children from the eight neighbouring communities to receive care in Calhuitz.

- A clear monitoring and evaluation plan needs to be created for the Calhuitz program so behavioural indicators can be tracked and assessed. Currently, there are no such plans in place and there is no clear estimate of the effect that these self help groups are having on the women and children in Calhuitz.
- There is a need for more trained attendants at the Casa Materna, especially during weekends. Currently only two nurses staff the Casa Materna and a doctor visits infrequently. These two nurses do not work on the weekends. Since self help groups (women's group) emphasize uptake of antenatal care, it is imperative the infrastructure id available to provide the care.
- The women's group intervention needs to be scaled up in other communities surrounding Calhuitz, such as Lolbatzam and Ucachoj after the effectiveness of the groups are proven in Calhuitz. Malnutrition is pervasive in these communities, so there is a need, if it is proven that this intervention is effective for it to be implemented in other communities.

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APPENDIX A: Table of Excluded Articles

Author, year	Title of Article	Location	Reason Excluded
Ali,M. et al, 2005	Helping northern Ethiopian communities reduce child mortality: population based intervention trial	Ethiopia	Does not involve women's group
Baker, E. et al.,2006	Early initiation of exclusive breastfeeding in large-scale community-based programmes in Bolivia and Madagascar	Bolivia, Madagascar	Does not include effects on infant health outcomes
Bang, A.T. et al., 1990	Reduction in pneumonia mortality and total childhood mortality by means of community-based intervention trial in Gadchiroli, India	India	Does not involve women's group
Bhutta, Z.A.et al., 2008	Improvement of perinatal and newborn care in rural Pakistan through community-based strategies: a cluster-randomised effectiveness trial	Pakistan	Packaged intervention
Bhutta,Z. A. et al., 2008	Implementing community-based perinatal care: results from a pilot study in rural Pakistan	Pakistan	Packaged intervention
Boone, P., 2007	Community health and medical provision: impact on neonates (the CHAMPION trial)	Andra Pradesh	Does not include effects on infant health outcomes
Darmstadt, G.L.	Evaluation of a cluster-randomized controlled trial of a package of community-based maternal and newborn interventions in Mirzapur, Bangladesh	Bangladesh	Does not involve women's group
Diallo, A.H. et al.,	Perinatal mortality in rural Burkina Faso: a prospective community-based cohort study	Burkina Faso	Does not involve women's group

Author, year	Title of Article	Location	Reason Excluded
Jakobsen, M.S., 2008	Promotion of exclusive breastfeeding is not likely to be cost effective in West Africa: a randomized intervention study from Guinea-Bissau.	Guinea-Bissau	Does not involve women's group
Jongpiputvanich, S., 1998	Difficulties in conducting participatory action research to prevent diarrhea in a slum area of Bangkok	Bangkok	Does not include effects on infant health outcomes
Kalanda, B.F., 2006	Breast and complementary feeding in relation to morbidity and growth in Malawaian infants	Malawi	Does not involve women's group
Kielmann, a.a., 1985	Control of deaths from diarrheal disease in rural communities: Design of an intervention study and effects on child mortality.	Egypt	Does not involve women's group
Kumar, V., 2008	Effect of community-based behavior change management on neonatal mortality in Shigavrh, Uttar Pradesh, India: a cluster-randomised controlled trial	India	Does not involve women's group
Kwast, B.E., 1996	Reduction of maternal and perinatal mortality in rural and peri-urban settings: what works?	Multiple	Not original intervention, a review
Lewycka, S. et al,	A cluster randomised controlled trial of the community effectiveness of two interventions in rural Malawi to improve health care and to reduce maternal, newborn and infant mortality	Malawi	Does not include effects on infant health outcomes
Martines, J.C., 1992	Breast feeding in the first six months	N/A	Does not involve women's group

Author, year	Title of Article	Location	Reason Excluded
Pokharel, G.P. et al., 1998	Nutrition education and mega-dose vitamin A supplementation in Nepal	Nepal	No infant health outcomes
Rao, S., 2003	Maternal activity in relation to birth size in rural India. The Pune Maternal Nutrition Study	India	Does not involve women's group
Rath, S.,	Explaining the impact of a women's group led maternal and newborn health outcomes: the Ekjut trial process evaluation community mobilisation intervention on		Does not include effects on infant health outcomes
Shankar, A.V., 2009	Programmatic effects of a large-scale multiple-micronutrient supplementation trial in indonesis: using community facilitators as intermediaries for behavior change	Indonesia	No women's group
Yoon,P. W., 1996	Effect of not breastfeeding on the risk of diarrheal and respiratory mortality in children under 2 years of age in Metro Cebu, the Phillipenes	Philippines	Does not involve women's group
(1985).	Large epidemic of cholera-like disease in Bangladesh caused by Vibrio cholerae O139 synonym Bengal.	Bangladesh	Does not involve women's groups or infant health
(1987).	Meeting the health promotion needs of Hispanic communities.	N/A	Does not involve women's groups or infant health
(1993).	WHO's Mother-Baby Package launched in French-speaking Africa.	Africa	No focus on women's support groups, infant health, a meeting of delegates
(1995).	Research to support household and community IMCI.	N/A	Implementation plan, not an intervention, does not involve

			women's groups or infant health
Arntzen, A. et al, 2008	Neonatal and postneonatal mortality by maternal education-- a population-based study of trends in the Nordic countries, 1981-2000	Nordic countries	Not in a developing country
Avitia Talamantes, M. (2000)	Impact of a community network of psychosocial support in perinatal health	Mexico	Does not fit definition of women's group
Barros, F.C. et al.,	Global report on preterm birth and stillbirth (3 of 7) evidence for effectiveness of interventions	Multiple	Not an original intervention, a review
Berer,M., 1999	Reducing perinatal HIV transmission in developing countries through antenatal and delivery care, and breastfeeding: supporting infant survival by supporting women's survival	Multiple	Not an original intervention, a review
Bhutta, Z.A. et al., 2008	What works? Interventions for maternal and child undernutrition and survival	Multiple	Not original intervention, a review
Black, R.E., 2008	Global, regional and national causes of child mortality in 2008: a systematic analysis	Multiple	Not original intervention, a review
Borghi, J. et al., 2005	Economic assessment of a women's group intervention to improve birth outcomes in rural Nepal	Nepal	Does not include the inclusion outcomes
Boschi-Pinto,C. et al.,	The Child Health epidemiology Reference Group reviews of the effectiveness of interventions to reduce maternal, neonatal and child mortality	Multiple	Not original intervention, a review
Bream,K. D., 2005	Barriers to and facilitaors for newborn resuscitation in Malawi, Africa	Malawi	Does not involve women's groups or infant health
Cacciator	Effect of support groups on post traumatic stress responses in women experiencing	The United	Not in a developing

e, J. , 2007	stillbirth	States of America	country, no infant health outcomes
Canosa, C. A., 1991	HIV infection in children	Multiple	Does not involve women's groups or infant health
Chalumeau, M., 2000	Risk factors for perinatal mortality in West Africa: a population based study of 20326 pregnancies. MOMA group.	West Africa	Does not involve women's groups or infant health
David,S., 2008	Promotion of WHO feeding recommendations: a model evaluating the effects on HIV-free survival in African children	Multiple	Not an original intervention, a review
Dis Manag Advis, 2002.	Non-traditional approach to pregnancy disease management yields surprising outcomes.	United States of America	Not in a developing country
Dubois, S., 1991	Twin pregnancy: the impact of the Higgins Nutrition Intervention Program on maternal and neonatal outcomes	Montreal	Does involve women's groups or infant health outcomes
Dunn, H.G., 1984	Social aspects of low birth weight	N/A	Not in a developing country
Edwards, L.E., 1987	Pregnancy in Hmong refugee women	Minnesota	Not in a developing country
Friberg, I.K. et al.,	Sub-Saharan Africa’s mothers, newborns, and children: how many lives could be saved with targeted health interventions?	Multiple	Not original intervention, a review

Heins, H.C., 1987	Social support in improving perinatal outcome: the Resource Mothers Program	United States of America	Not in a developing country
Kinney, M.V.,	Sub-Saharan Africa's mothers, newborns, and children: where and why do they die?	Sub-Saharan Africa	Not original intervention, a review
Kollee, L.A., 2009	Obstetric interventions for babies born before 28 weeks of gestation in Europe: results of the MOSAIC study	Europe	Not in a developing country
McCloskey, L. et al., 1999	A community-wide infant mortality review: findings and implications	Multiple	Not original intervention, a review
McEnery, G., et al., 1986	The effectiveness of antenatal education of Pakistani and Indian women living in this country	East London	Not in developing country
McGlade, M.S. et al., 2004	The Latina paradox: an opportunity for restructuring prenatal care delivery	United States of America	Not in developing country
McMaster, P et al., 2000	Outcome of neonatal care in Port Moreby, Papa New guinea: a 19 year review	Papa New Guinea	Not original intervention, a review
Morrison, J. et al., 2008	How did formative research inform the development of a women's group intervention in rural Nepal?	Nepal	Does not involve women's groups or infant health
Mott, S.H., 1984	A note on the determinants of breastfeeding duration in an African country	Kenya	Does involve women's groups or infant health outcomes
Nishiuchi, M.,	Mothers in community health care activities-The Suita Mother's club	Japan	Not in a developing

1985			country
Osrin, D., et al., 2003	Implementing a community-based participatory intervention to improve essential newborn care in rural Nepal	Nepal	Not in a developing country
Pampel, F.C., 1986	Patterns and determinants of infant mortality in developed nations, 1950-1975	Multiple	Not original intervention, implementation startegy
Prasad,B. et al., 1995	Impact and sustainability of a baby friendly training intervention for staff at an Indian district hospital on initiation of breastfeeding and use of prelacteal feeds by mothers	India	Not in developing country
Rogers, M., 1996	Impact of a social support program on teenage prenatal care use and pregnancy outcome	United States of America	Does not involve women's groups or infant health
Rosato, M.,2006	Women's groups' perceptions of maternal health issues in rural Malawi	Malawi	Not in a developing country
Shrimpton, R., 2009	Multiple micronutrient supplementation during pregnancy in developing-country settings: policy and program implications of the results of a meta-analysis	Multiple	No effects on infant outcome noted
Tupasi, T.E., 1989	Child care practices of mothers: implications for intervention in acute respiratory infections	Phillipines	Not original intervention, a meta-analysis
Victora, C.G.	Global report on preterm birth and stillbirth (4 of 7) delivery of interventions	Multiple	Does not involve women's groups or infant health
Zhang, T.	An evaluation of effects of intervention on maternal and child health in the rural areas of	China	Not in a developing

et al., 2004	China		country
Bhutta et al, 2009	A comparative evaluation of multiple micronutrient and iron-folic acid supplementation during pregnancy in Pakistan: impact on pregnancy outcomes	Pakistan	Does not involve women's groups or infant health
Villar et al, 1992	A randomized trial of psychosocial support during high-risk pregnancies. The Latin American Network for Perinatal and Reproductive research.	Latin America	Does not involve women's groups or infant health
Kirwood et al, 2010	NEWHINTS cluster randomized trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol.	Ghana	Does not involve women's groups or infant health
Johio, A.H., 2005	An intervention involving traditional birth attendants and perinatal and maternal mortality in Pakistan	Pakistan	Does not involve women's groups or infant health
More, N.S., 2008	Cluster-randomized controlled trial of community mobilization in Mumbai slums to improve care during pregnancy, delivery, postpartum and for the newborn	Mumbai	Does not include effects on infant health outcomes
Kaestel, P. et al, 2005	Effects of prenatal multimicronutrient supplements on birth weight and perinatal mortality: a randomized, controlled trial in Guinea-Bissau	Guinea-Bissau	Does not include women's groups
Ceesay, S. et al., 1997	Effects on birth weight and perinatal mortality of maternal dietary supplements in rural Gambia: 5 year randomized controlled trial.	Gambia	Does not involve women's groups or infant health
Zeng, L et al, 2008	Impact of micronutrient supplementation during pregnancy on birth weight, duration of gestation, and perinatal mortality in rural western China: double blind cluster randomized controlled trial	China	Not in a developing country

Menendez, C. et al, 2010	Malaria prevention with IPTp during pregnancy reduces neonatal mortality	Mozambique	Does not involve women's groups or infant health
Kafatos, A.G., 1991	Maternal and infant health education in a rural Greek community	Greece	Not in a developing country
Mbori-Ngacha, D. et al, 2001	Morbidity and mortality in breastfed and formula fed infants of HIV-1-infected women: a randomized controlled trial	Kenya	Does not involve women's groups or infant health
Christian, P et al, 2008	The effect of maternal micronutrient supplementation on early neonatal morbidity in rural Nepal: a randomised, controlled, community trial	Nepal	Does not involve women's groups or infant health

APPENDIX B

CORE VARIABLES FOR EACH STUDY ABSTRACTED INTO THE REVIEW DATABASE
1. The Warmi study: Bolivia
Study identifiers and context: the study took place in three zones of Inquivisi province; Inquivisi, Licoma and Circuata, Bolivia. The health care system in this province is weak, with each zone having only one healthcare personnel. The province is remote and rural. The total study population was 15,000 people.
Study design and limitations: The study used a quasi-experimental design where comparison was based on pre-post intervention data. There was not a control group and no randomization involved in this study.
Intervention characteristics: The community action cycle was used with 50 women's organizations. Data for the study came from results in a community registry. The intervention also involved the strengthening of existing women's organizations.
Outcome effects: Perinatal mortality reduced from 117 per 1000 before the intervention to 43.8 per 1000 births after the intervention.
Summary of Limitations: There was no control group for this study and mortality data represent results from the whole Inquivisi community registry and not specifically from the intervention population. The analysis data was based on results pre and post intervention.

CORE VARIABLES FOR EACH STUDY ABSTRACTED INTO THE REVIEW DATABASE-CONTINUED
2. <u>The MIRA Makwanpur trial: Nepal</u>
Study identifiers and context: The study took place in a remote, rural and mountainous area of Nepal called Makwanpur, Nepal where an estimated 90% of women give birth at home. 57% of women in rural areas of Nepal cannot read, a fact that stunts the level at which women can be involved in key decision making. The infant mortality rate is 64 per 1000 live births, neonatal mortality is at 39 per 1000 livebirths and perinatal mortality stands at 47 per 1000 live births. The Nepal study that started in February 2001, came at a time when mortality rates among children were in dire need of reduction
Study design and limitations: The study utilized a cluster randomized controlled design to assess the effect of the women's group on birth outcomes. 42 village development committees (VDC) in Makwanpur were randomized and matched on geography, population density and ethnicity forming 21 pairs. The randomization was repeated to yield 12 pairs of VDCs, with a VDC from each pair randomized to either the intervention or control group. The total study area was 170,000 people.
Intervention characteristics: Participants were enrolled from September 1999 to November 2000 and potential cohorts were interviewed from March 2001 to July 2001. Starting in February 2001, the menstrual status of the women was tracked with evidence of pregnancy classified as a woman having no menstruation in 3 months. The study consisted of married women between the ages of 15 and 49 who were of reproductive age (MWRA). Women who weren't between 15 and 49, and who were permanently separated and had no potential for conceiving during the study period were excluded from the study. The women were interviewed twice (at 7 months after gestation and 1 month postpartum). A verbal autopsy was done to get information on neonatal deaths. Health care strengthening consisted of capacity building of government health staff, female community health workers and traditional birth attendants, increase in equipment (resuscitaires, phototherapy units etc) and consumables (neonatal drugs). This was done in both control and intervention areas.
Outcome effects: Due to the intervention there was a 30% reduction in neonatal mortality rate and this result was statistically significant (adjusted odds ratio -OR 0.70, 95% CI 0.53-0.94). There was no difference between stillbirth rates between intervention and control groups (1.06, 95% CI 0.76-1.47).
Summary of limitations: One of the VDCs was excluded from the study because of security concerns. It is uncertain if the inclusion of this VDC would have altered results. Security issues led to meetings being postponed in areas included in the study. Without health services strengthening, the intervention might not have been as successful.

CORE VARIABLES FOR EACH STUDY ABSTRACTED INTO THE REVIEW DATABASE-CONTINUED
3. The Jharkhand and Orissa trial: India
Study identifiers and context: Three districts in Jharkhand and Orissa, India namely Saraikela Kharswan, West Singhbhum and Keonjhar served as sites for this study. As with Nepal, this intervention was especially needed in this location because of the high mortality rates seen in India as a whole. 21% of all child deaths and 25 % of all neonatal deaths are concentrated in India. Additionally, Jharkhand and Orissa is characterized by a high level of poverty and is home to one of the most severely underserved groups in India, the Adivasis which constituted 58-70% of the study population.
Study design and limitations: a clinical randomized controlled design was used. The study took place between July 31, 2005 and July 30, 2008 and made use of 12 clusters per district randomly allocated to intervention and control groups as shown in figure 1 below. The selection of areas for the study was done with the help of an external observer from a NGO who drew numbers from a basket. The total estimated population for this study was 228, 186 with a mean of 66338 people within each group of 12 clusters.
Intervention characteristics: The study utilized 172 existing women's groups and 72 additional groups to cover 18 intervention clusters. The Community action cycle was used as the intervention technique. A total of 20 meetings were held over the study period, with meetings being held monthly. Key informants, either traditional birth attendants or village members reported births, maternal and newborn deaths and deaths of women of reproductive age each month. Reports were obtained by interviewing mothers, relatives of the mothers (if the mothers had died) or other individuals present at the time of death (verbal autopsy).The health services component of this study involved formation of health committees by community members and connecting community members with government health staff from 7 clusters per district in Jharkhand.
Outcome effects: At baseline, NMR in this study was 58 per 1000 live births. After 3 years of the intervention there was a 32 % reduction in NMR (adjusted OR 0.68, 95% CI 0.59-0.78, p=0.0005) and a 21% reduction in PMR (adjusted OR 0.79, 95% CI 0.69-0.91, p=0.0005). Between intervention and control groups, there was no difference in stillbirth rate (adjusted OR 1.05, 95% CI 0.86-1.28).
Summary of limitations: Surveillance team was aware of intervention and control groups. Dome women migrated out of home clusters.
4. Bogra, Faridpur and Moulavibazar trial: Bangladesh
Study identifiers and context: 45% of deaths in Bangladesh occur in the first month of life and 85% of births occur at home. The study took place in the districts of Bogra, Faridpur and Moulavibazar between February 1, 2005 and December 31, 2007. Each district consisted of 6 unions and areas that were selected for the study were close to an active Diabetic Association of Bangladesh (BADAS). Other stipulations for areas of inclusion were based on recommendations from BADAS representatives; who recommended specifically that areas be selected that had limited access to perinatal healthcare and that were close in proximity to BADAS.

CORE VARIABLES FOR EACH STUDY ABSTRACTED INTO THE REVIEW DATABASE-CONTINUED
Study design and limitations: The study made use of a cluster randomized controlled trial as well as a factorial design. For the factorial design component, the community based women's group intervention was compared to an intervention that involved capacity strengthening of traditional birth attendants in bag-valve resuscitation of neonates with symptoms of birth asphyxia. The study population was 503, 163 people. Each union was randomly assigned to intervention or control groups with the help of four project staff and two external staff in two phases to allocate participants to the two interventions. Study investigators and participants were not blinded to group allocation but the staff had no knowledge of the health and socioeconomic status of union clusters.
Intervention characteristics: The study group consisted of married women of reproductive age (from 15 to 49) as well as their mother in laws, adolescents, and other women who had given birth during the study period. It utilized an open cohort, meaning participants could enter the study at anytime. The community action cycle was utilized and made relevant to maternal and child issues. The health services strengthening consisted of capacity building of key health personnel and linking the community services to health services.
Outcome effects: The adjusted risk ratio for neonatal mortality was 0·90 (95% CI 0·73–1·10) signifying that those mothers who were exposed to the women's group intervention were 10% less likely to have a baby that died than mothers who did not receive the intervention. This result was not however, statistically significant and may point to the myriad of limitations associated with this particular study. There was a 4% decrease in Perinatal mortality rate between intervention and control groups (adjusted RR 0.96, 95% CI 0.88-1.04) and still births showed no difference between intervention and control groups (adjusted RR 1.00, 95% CI 0.82-1.21). Results seen for this trial were not statistically significant.
Summary of limitations: Questions arise as to why fewer clusters were chosen for this study compared to other trials, why although there was a lower NMR for the intervention group, there were reductions in NMR over time for the control group as well, and why maternal mortality was greater among women in women's group intervention than in the control group. Additionally, community health workers were only able to attend less than 5% of all births. Facilitators had to lead 18 meetings per month. There was a low retention rate for facilitators and supervisors, disruptions in meetings which reduced support for community mobilization. Some coordinators were not able to provide support to facilitators because they lived far away. There was a flood in one of the intervention unions in 2007. Also other NGO's in the area supported women's groups and in those groups women were given incentives for their attendance compared to this study.

CORE VARIABLES FOR EACH STUDY ABSTRACTED INTO THE REVIEW DATABASE-CONTINUED

5. The Sylhet trial: Bangladesh

Study identifiers and context: The sub-districts involved were Beanibazar, Zakiganj and Kanaighat, with the clusters from each sub-district receiving either the community care intervention, the home care-intervention or no intervention. Sylhet district was particularly suited to receive the intervention because it has the highest NMR, poor access to healthcare and due to the presence of other NGOs in the area that can continue the interventions.

Study design and limitations: Using a computerized random number generator, the 24 clusters were either randomized to the community care intervention, the home care intervention or no intervention arms (8 clusters in each arm). 36, 059 women relegated to the home care arm, 40, 159 to the community care arm and 37598 to the no intervention arm.

Intervention characteristics: The study group were women of reproductive age (15-49) .The home care arm utilized one female community health worker for every four villages to provide essential newborn care, to clinically assess neonates, to manage and control sickness among neonates (either by referring them to sub-district hospitals or with the permission of family, treating the neonate at home), to identify and record pregnancies and to promote birth and newborn pregnancies. In the home care arm too, community meetings with the women were held. The community care strategy appeared to be primarily used to disseminate information on birth and newborn preparedness as well as a means to encourage women to seek antenatal care in a group setting. To gather information on NMR, surveys were utilized and the recall period was three years.

Outcome effects: Baseline results indicate the mother's age and education, birth order, child's se, and household wealth was similar across study arms and suggests that any changes seen after baseline should have been due to the study. NMR in the home care arm was reduced by 34% (adjusted RR 0.66; 95% CI 0.47-0.93) compared to the no intervention group and there was no reduction in NMR for the community care arm (adjusted RR 0.95; 95% CI 0.69-1.31) over the last six months of the study. Throughout the study period there appeared to be decreases in NMR for the home care arm, although a majority of these reductions were not statistically significant. Effects for the community care arm seemed to be the same throughout the study period.

Summary of limitations: Recall biases associated with misreporting of information could have potentially taken place in this study since recall appears to be the primary mode of collecting the mortality data. Although this would be the case across the study arms, to ensure maximum accuracy of data, other data sources should have also been used.